

### REMARKS

Applicants have amended claim 31, and have cancelled claims 1-30, during prosecution of this patent application. Applicants are not conceding in this patent application that the subject matter encompassed by said amended and cancelled claims are not patentable over the art cited by the Examiner, since the claim amendments and cancellations are only for facilitating expeditious prosecution of this patent application. Applicants respectfully reserve the right to pursue the subject matter encompassed by said amended and cancelled claims, and to pursue other claims, in one or more continuations and/or divisional patent applications.

The Examiner rejected claims 31, 39-41 and 61 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner rejected claims 31-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by FR 7037 (ROUSSEL-UCLAF).

The Examiner rejected claims 31-34, 39-41 and 61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over FR 7037 (ROUSSEL-UCLAF) in view of Grover et al. (Pediatr Res., 2002, Dec.; 52(6):907-12).

Applicants respectfully traverse the § 112, § 102 and § 103 rejections with the following arguments, in which Applicants refer *infra* to the specification of the present patent application in US 2005/0069518 published March 31, 2005.

**35 U.S.C. § 112, First Paragraph: Claims 31, 39-41 and 61**

The Examiner rejected claims 31, 39-41 and 61 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner argues: "The specification discloses nicotinic acid or nicotinic acid analog where said nicotinic acid is conjugated to polyvinyl alcohol, acrylic acid ethylene co-polymer, polyethylene glycol (PEG) or polylactic acid, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims 31, 36-41 and 61 are directed to encompass "analogs" or "a polymeric form" which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these meet the written description provision of 35 USC 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompasses a myriad of possibilities. To the extent that no structure function data is disclosed in connection with these functionally described compounds to correlate, or there is not disclosed correlation established between these functional drugs and the contemplated desired therapeutic effect to be achieved in practicing the instant invention, the specification provides insufficient written description to support the genus encompassed by the claims."

In response, Applicants cite *In re Alonso*, 88 USPQ2d 1849 (Fed. Cir. October 30, 2008, 88 USPQ2d 1849) as being the **latest decision** by the Federal Circuit how a patent application may satisfy the written description requirement with respect to a genus. The *Alonso* court asserted that there are several alternatives for satisfying the written description requirement in describing a genus; i.e. by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or some combination of such characteristics." *Id.* at 1852.

The written description requirement is satisfied for independent claim 31 in accordance with *In re Alonso* via identification of a representative number of species of the genus of polymeric forms of nicotine and representative number of species of the genus of a nicotinic acid derivative, which is disclosed in the specification in the form of nicotine and nicotinic acid each conjugated to polymers via covalent or non-covalent linkages. See US 2005/0069518, Par. [0047], lines 1-4 ("Representative compositions of the present invention include Nicotine, nicotinic acid, analogs thereof conjugated to polymers. Conjugation with polymers can be either through covalent or non-covalent linkages.").

A representative species of the genus of polymeric forms of nicotine and nicotinic acid is disclosed in US 2005/0069518, Par. [0047], lines 4-6 which states that nicotine and nicotinic acid may each be conjugated to a polymer via an ester linkage. For example, FIG. 2 depicts a chemical structure showing repeating units of a polymeric form of nicotinic acid, namely nicotinoyl ester of polyvinyl alcohol, comprising an ester linkage, as described in US 2005/0069518, Par. [0030].

Another representative species of the genus of polymeric forms of nicotine and nicotinic acid is disclosed in US 2005/0069518, Par. [0047], lines 4-6 which states that nicotine and nicotinic acid may each be covalently conjugated to a polymer via an anhydride linkage. For example, FIG. 3 depicts a chemical structure showing repeating units of a polymeric form of nicotinic acid, namely nicotinoyl anhydride of acrylic acid-ethylene co-polymer, comprising an anhydride linkage, as described in US 2005/0069518, Par. [0031].

Another representative species of the genus of polymeric forms of nicotine and nicotinic acid is disclosed in US 2005/0069518, Par. [0050], lines 1-6 which states that nicotine and nicotinic acid may each be non-covalently conjugated to a polymer by being entrapped in polylactic acid (PLA). For example, FIG. 4 depicts a polymeric form of nicotinic acid, namely 3-nicotinic acid containing PLA beads, as described in US 2005/0069518, Par. [0032].

Another representative species of the genus of polymeric forms of nicotine and nicotinic acid is disclosed in US 2005/0069518, Par. [0049], lines 1-3 which states that nicotine and nicotinic acid may each be conjugated to polyethylene glycol (PEG).

Therefore, in accordance with the decision in *In re Alonso*, Applicants respectively contend that independent claim 31 and dependent claims 39-41 and 61 satisfy the written description requirement under 35 U.S.C. 112, first paragraph.

**35 U.S.C. § 102(b): Claims 31-34**

The Examiner rejected claims 31-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by FR 7037 (ROUSSEL-UCLAF).

Applicants respectfully contend that FR 7037 does not anticipate claim 31, because FR 7037 does not teach each and every feature of claim 31. For example, FR 7037 does not teach a composition comprising both *nicotine* (or a polymeric form thereof) and a nicotinic acid analog comprising a nicotinic acid derivative as required by claim 31. Applicant asserts that FR 7037 does not mention nicotine.

The Examiner argues: “In response to applicant's argument that FR 7037 does not teach a composition comprising both nicotine (or a polymeric form thereof) and a nicotinic acid derivative, the examiner recognizes that applicant has received an action on the merits for the originally elected invention which is directed to a Group II invention along with a composition *comprising* nicotine, nicotinic acid analogs or polymeric forms thereof (see applicant's Response filed 09/10/2008). Since this election was made without traverse, claim 31 is construed to mean a composition comprising nicotine, nicotinic acid analogs or polymeric forms or derivatives.” (emphasis added).

In response, Applicants note that the restriction referred to by the Examiner in which Group II was elected was a restriction between a method (Group I) and a composition (Group II). Applicants respectfully contend that the claimed composition comprising both nicotine (or a polymeric form thereof) and a nicotinic acid analog comprising a nicotinic acid derivative is within the scope of the Group II, since the word “*comprising*” in the text describing Group II is open-ended and thus does not preclude adding substances (e.g., nicotine or a polymeric form thereof) to a composition that *comprises* a nicotinic acid analog comprising a nicotinic acid

derivative.

Based on the preceding arguments, Applicant respectfully maintains that FR 7037 does not anticipate claim 31, and that claim 31 is in condition for allowance. Since claims 32-34 depend from claim 31, Applicant contends that claims 32-34 are likewise in condition for allowance.

**35 U.S.C. § 103(a): Claims 31-34, 39-41 and 61**

The Examiner rejected claims 31-34, 39-41 and 61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over FR 7037 (ROUSSEL-UCLAF) in view of Grover et al. (Pediatr Res., 2002, Dec.; 52(6):907-12).

Applicant respectfully contends that claim 31 is not unpatentable over FR 7037 in view of Grover, because FR 7037 in view of Grover does not teach or suggest each and every feature of claim 31. For example, FR 7037 in view of Grover does not teach or suggest a composition comprising both *nicotine* (or a polymeric form thereof) and a nicotinic acid analog comprising a nicotinic acid derivative as required by claim 31. Applicant asserts that FR 7037 does not mention nicotine. Applicant further asserts that Grover does not mention nicotine.

The Examiner argues: "In response to applicant's argument that FR 7037 does not teach a composition comprising both nicotine (or a polymeric form thereof) and a nicotinic acid derivative, the examiner recognizes that applicant has received an action on the merits for the originally elected invention which is directed to a Group II invention along with a composition *comprising* nicotine, nicotinic acid analogs or polymeric forms thereof (see applicant's Response filed 09/10/2008). Since this election was made without traverse, claim 31 is construed to mean a composition comprising nicotine, nicotinic acid analogs or polymeric forms or derivatives." (emphasis added).

In response, Applicants note that the restriction referred to by the Examiner in which Group II was elected was a restriction between a method (Group I) and a composition (Group II). Applicants respectfully contend that the claimed composition comprising both nicotine (or a polymeric form thereof) and a nicotinic acid analog comprising a nicotinic acid derivative is within the scope of the Group II, since the word "*comprising*" in the text describing Group II is

open-ended and thus does not preclude adding other substances (e.g., nicotine or a polymeric form thereof) to a composition that ***comprises*** a nicotinic acid analog comprising a nicotinic acid derivative.

Based on the preceding arguments, Applicant respectfully maintains that claim 31 is not unpatentable over FR 7037 in view of Grover, and that claim 31 is in condition for allowance. Since claims 32-34, 39-41 and 61 depend from claim 31, Applicant contends that claims 32-34, 39-41 and 61 are likewise in condition for allowance.



### CONCLUSION

Based on the preceding arguments, Applicants respectfully believe that all pending claims and the entire application meet the acceptance criteria for allowance and therefore request favorable action. If the Examiner believes that anything further would be helpful to place the application in better condition for allowance, Applicants invites the Examiner to contact Applicants' representative at the telephone number listed below. The Director is hereby authorized to charge and/or credit Deposit Account 19-0513.

Respectfully submitted,  
FOR: MOUSA-6043

BY:

Dated: December 10, 2009

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